

1 **Claims 1 – 16 (cancelled)**

1 **Claim 17. (new)** A classification and management system for patients with
2 lower extremity arterial occlusive disease comprising the steps of:

- 3 • examining a patient at a healthcare facility with lower extremity arterial
4 occlusion disease,
- 5 • collecting patient data including physically observable conditions of the
6 patient's lower extremities and noninvasive arterial pressure and blood
7 flow data,
- 8 • recording the collected patient data,
- 9 • transmitting said collected patient data to an evaluating authority,
- 10 • comparing said collected patient data against a medically accepted set
11 of disease specific criteria at the evaluating authority to classify
12 patients as "potentially at risk" and "not at risk" of developing
13 complications of arterial occlusive disease,
- 14 • transmitting said preliminary classification to the healthcare facility,
- 15 • referring those patients classified as "potentially at risk" of arterial
16 occlusive disease to an accredited laboratory for noninvasive vascular
17 evaluation,
- 18 • evaluating those "potentially at risk" patients at the accredited
19 laboratory against medically accepted criteria,
- 20 • recording the results of said noninvasive vascular evaluation at the
21 accredited laboratory,
- 22 • transmitting said recorded results to the evaluating authority for final
23 classification,
- 24 • classifying each patient at the evaluating authority against medically
25 accepted criteria as "at risk" or "not at risk" of developing arterial
26 occlusive disease,
- 27 • transmitting said "at risk" or "not at risk" patient final classification to the
28 healthcare facility,
- 29 • recording said "at risk" or "not at risk" patient final classification at the
30 healthcare facility,
- 31 • referring patients having a final classification of "at risk" for critical
32 ischemia with associated extremity lesions and patients with
33 noninvasive evidence of severe ischemia to a vascular surgery facility

34 for vascular surgical assessment to determine whether
35 revascularization is necessary,

36 • assessing such "at risk" patients against medically accepted criteria as
37 "clinical indication for operation" or "no indication for operation" at the
38 vascular surgery facility,

39 • electing revascularization and periodic management system evaluation
40 at the healthcare facility or routine wound care and periodic revaluation
41 at the healthcare facility by patients assessed as "clinical indication for
42 operation",

43 • monitoring patients assessed as "no indication for operation" by the
44 healthcare facility with increased precautions to monitor for detection of
45 any visible deterioration of the patient's lower extremities that would
46 require reassessment,

47 • referring patients having ulcers, pain or gangrene at the time of "no
48 indication for operation" assessment for reassessment,

49 • referring patients classified as "no indication for operation" that develop
50 ulcers, pain and/or gangrene to the vascular surgery facility for
51 reassessment,

52 • reassessing the referred patient at the vascular surgery facility against
53 medically accepted criteria as "no indication for operation" or "clinical
54 indication for operation",

55 • transmitting the reassessment of "no indication for operation" or "clinical
56 indication for operation" to the evaluating authority for reevaluation as
57 "no indication for operation" or "clinical indication for operation",

58 • transmitting the reevaluation to the healthcare facility with the
59 appropriate medical procedure and regimen,

60 • treating and monitoring patients classified as "not at risk", "at risk" and
61 assessed as "no indication for operation" or "clinical indication for
62 operation" at the healthcare facility,

63 • providing "not at risk" patients without limb ulcers routine care and
64 precautions at the healthcare facility,

65 • providing "not at risk" patients with limb ulcers routine wound care at the
66 healthcare facility,

67 • providing "not at risk" patients with limb ulcers periodic reevaluation by
68 the evaluating authority,

69 • providing “at risk” patients assessed as “no indication for operation” or
70 “operation not elected by patient”, and “clinical indication for operation”
71 patient undergoing revascularization at the vascular surgery facility with
72 intensive wound care at the healthcare facility, and,
73 • providing periodic reevaluations of “at risk” patients assessed as “no
74 indication for operation” or “operation not elected by patient” with
75 increased precautions at the healthcare facility.